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Efficacy and Safety of CGMS Combined with Insulin Pump CSII in the Treatment of Newly Diagnosed Severe Type 2 Diabetes

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Abstract: To investigate the efficacy and assess the safety of dual C therapy (CGMS combined with CSII) in the treatment of primary severe type 2 diabetes mellitus (T2DM). In this paper, 100 newly diagnosed severe type 2 diabetes patients admitted to our hospital from January 2020 to December 2021 were selected and divided into the control group (multiple subcutaneous insulin injections+finger tip blood glucose monitoring) and the observation group (double C therapy) with 50 cases each. The general information, blood glucose reaching time, blood glucose drift, insulin dosage, blood glucose, blood lipid level, fasting glucose (FPG), blood glucose 2h after meal (2hPG) The levels of hemoglobin (HbAlc), total cholesterol (TC), triglyceride (TG), low-density lipoprotein cholesterol (LDL-C) and the therapeutic effect. In the observation group, the time taken to reach the blood glucose standard was recorded as 5.36±1.04d, shorter than that of the control group as 7.64±1.11d (P<0.05), and the blood glucose drift was recorded as 7.32±1.54cd mmol/L and insulin dosage was recorded as 0.65±0.08U/kg, both better than that of the control group as 5.17±1.03cd mmol/L, 0.51±0.02U/kg (P<0.05). 0.02 U/kg in the control group (P < 0.05); after treatment, FPG in the observation group was measured as 6.22 ± 0.04) mmol/L, 2hPG was measured as (9.52 ± 1.14) mmol/L, and HbAlc was (6.11 ± 0.65) %, which were better than the corresponding levels in the control group (P<0.05). The TC, TG, and LDL-C levels in this group were [(4.01±0.23) mmol/L, (1.56±0.44) mmol/L, and (3.01±0.23) mmol/L], respectively, all of which were lower than those in the control group (all P<0.05). ALT, CRE, and BUN were found to be comparable between the two groups before and after treatment (P>0.05); the overall effective rate was higher in the observation group (98.00% vs. 86.00%) and the incidence of hypoglycemia was lower in the observation group (0.2% vs. 18.00%) compared with the control group(P<0.05). The combination of CGMS and CSII in T2DM can improve the effect of blood glucose control, reduce the amount of insulin used to treat patients, shorten the time of reaching the standard of blood glucose, and reduce the incidence of hypoglycemia.

1. Introduction

The onset of diabetes is hidden. Most people occasionally find that the blood sugar is higher than normal for a single time, or seek medical advice with diabetes complications, among which T2DM is the most common [1-2]. At present, the etiology of T2DM remains to be explored, and various mechanisms are involved in the occurrence and development of T2DM. It is generally accepted that the oxidative stress and glucose lipid metabolism disorder caused by insulin resistance in T2DM patients are more volatile, the disease develops faster, the incidence rate of complications is higher, and the prognosis is worse. Therefore, rapid and accurate control of blood glucose to keep it stable in the normal range for a long time is the key to prevent the development of T2DM and its complications [3-4]. Continuous subcutaneous insulin pump infusion (CSII) is a method of β Stimulation of cell function and insulin sensitivity can regulate hyperglycemia caused by liver glucose input, thus maintaining normal blood glucose level [5-6]. Continuous glucose monitoring system (CGMS) is a new technology developed in recent years. It can dynamically monitor the blood glucose values of patients throughout the day and also reflect the fluctuation of blood glucose. At present, CGMS is widely used as an indication. This monitoring technology was summarized by foreign experts as an effective supplement to traditional blood glucose monitoring [7]. In addition, CGMS has important value in the detection of asymptomatic hypoglycemia compared with self-monitoring blood glucose [8-9]. Therefore, this article uses "double C therapy" to apply to newly diagnosed severe T2DM, and discusses its application effect. The report is as follows.

1.1 Object and Method

Randomize 100 newly diagnosed patients with severe T2DM from January 2020 to December 2021, and randomly divide them into two groups (50 cases in the control group and 50 cases in the observation group) by drawing lots. Inclusion criteria: ① The diagnosis of all newly diagnosed severe T2DM patients meets the diagnostic criteria of the Chinese Guidelines for the Prevention and Treatment of Type 2 diabetes in 2020 [10]; ② The patients showed weight loss, excessive food and drink, hot hands and feet, dry stool, thirst, hyperhidrosis, fatigue, palpitations and other symptoms; ③ Patients with elevated blood glucose, i.e., 2h PG level>11.1 mmol/L, FPG>7.0 mmol/L, and random blood glucose level>11.1 mmol/L; ④ The level of TC was<6.22mmol/L, the level of LDL-C was<4.14mmol/L, and the level of TG was<5.0mmol/L. Exclusion criteria: ① Special population (including pregnant or lactating women); ② People who are allergic to hypoglycemic drugs or other related drugs; ③ One month before admission, patients with surgical hyperosmotic coma or trauma; ④ Patients with diabetes ketoacidosis, hyperthyroidism or type 1 diabetes; ⑤ Patients with one or more important organ failure/dysfunction, blood disease, mental disease or malignant tumor; ⑥ Poor compliance, not taking medicine strictly according to the doctor's advice. Observation group: male: female (28 cases vs 22 cases); Age 36~70 (57.45 ±9.71) years; BMI was (25.41 ±2.72kg/m2). In the control group, male: female (26 cases vs 24 cases), age 38~72 (58.19 ± 6.78 years); BMI is (25.20 ± 3.11) kg/m2. The baseline data of the two groups were equivalent (P>0.05).

1.2 Methods

All patients should stop using other hypoglycemic drugs immediately after admission, carry out health education on disease treatment and other knowledge, and give basic intervention such as diet, exercise, exercise and medication. The control group was given subcutaneous insulin injection and finger tip blood glucose monitoring. At different time points (including before meal, after meal and before sleep), the patients monitored blood glucose with finger tip blood glucose meter, with the

frequency of 7 times/day. The injection volume was adjusted according to the results. Insulin was injected subcutaneously before breakfast, lunch, dinner and bedtime, 4 times a day. The observation group was treated with "double C therapy", and the scheme was as follows: (1) CGMS was placed. The patient installed CGMS on the day of admission. Before installation, the abdomen was cleaned and disinfected. The electrical signal tester was used to detect the signal connection of CGMS instrument. After checking the battery power, the guide device was used to push the device into the skin at the outside of the patient's arm, pull out the guide pin, and fix the probe sensor. (2) CGMS is used. After installation, connect the cable, set the electrical signal at 20~200mA, and continue to initialize for 1h. Input the first fingertip blood glucose value. Input the blood glucose value four times a day before going to bed and eating. After continuous input for three days, analyze the blood glucose changes. (3) CSII drug quantity calculation: calculate the daily total insulin according to CGMS blood glucose change chart and the patient's body mass, with reference to the influence of diet, exercise, emotional changes and other factors. The proportion of daily basal insulin pump volume and meal supplement volume was 50%, which was stored in the insulin pump container. (4) The CSII was placed. One day after the CGMS was installed, the insulin pump was fixed on the patient's abdomen (5cm from the belly button), and the pump storage device was placed on the patient's trousers waist or pocket. Adjust the dosage according to the blood glucose monitoring results. Note: Inform patients and their families about the characteristics and operation methods of CGM and CSII instruments; Instruct the patient to keep it properly to prevent water ingress, distortion, discounts, interference from the battery, and unauthorized disassembly. Both groups were treated for 14 days.

1.3 Observations

(1) The baseline data of the two groups (including gender distribution, age distribution, blood glucose, blood lipid, body mass index, etc.) were compared. (2) The time taken for the two groups to reach the standard of blood glucose was recorded, and the blood glucose drift and actual insulin consumption of the two groups were calculated and counted. (3) The blood glucose (FPG, 2hPG, HbAlc) and blood lipid levels (TC, TG, LDL-C) were measured with an automatic biochemical analyzer. (4) Efficacy evaluation: after treatment, the blood glucose level of the two groups was measured and the efficacy was evaluated accordingly. Significant effects were observed: after treatment, the FPG level was $\geqslant$ 6.39 mmol/L, and the PG level was $\geqslant$ 7.8 mmol/L; Effective: after treatment, the FPG level was $\geqslant$ 7.8mmol/L, and the PG level was $\geqslant$ 11.1mmol/L at 2h; Ineffective: the blood glucose control is not ideal or aggravated. (Significant and effective cases)/total cases $\times$100% of the total effective rate is calculated.

1.4 Statistical Analysis

SPSS22.0 software was used for analysis. The measurement data were analyzed by independent sample t test and paired t test within the group; X2 test was used for counting data between groups. $P < 0.05$ means there is statistical difference.

2. Results

2.1 Comparison of Two Groups of Baseline Data

The baseline data (age, course of disease, weight, blood glucose) of the two groups were equivalent ($P>0.05$), as shown in Table 1.

Table 1. Comparison of baseline data between two groups ()

group	Number of cases (n)	Age	Course of disease (year)	Weight (kg/m2)	Hemoglobin (%)	Fasting blood glucose (mmol/L)	Blood glucose 2h after meal (mmol/L)
control group	50	58.26±6.53	7.32±3.54	25.13±3.07	11.58±2.27	15.67±2.24	20.46±5.16
Observation group	50	57.34±9.66	6.87±2.13	25.38±2.69	12.32±1.57	15.36±3.52	21.35±3.71
t	——	0.558	0.770	0.433	1.896	0.525	0.990
p	——	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

2.2 Comparison of Blood Glucose Control Effect and Insulin Dosage between the Two Groups

The time of blood glucose reaching the standard in the observation group was shorter than that in the control group ($P < 0.05$), and the blood glucose drift and insulin dosage were lower than those in the control group ($P < 0.05$), as shown in Table 2 and Figure 1

Table 2. Comparison of blood glucose reaching time, blood glucose drift and insulin dosage between the two groups ()

group	Number of cases (n)	Time of blood glucose reaching the standard (d)	Blood glucose drift (cd mmol/L)	Insulin dosage (U/kg)
control group	50	7.64±1.11	7.32±1.54	0.65±0.08
Observation group	50	5.36±1.04	5.17±1.03	0.51±0.02
t	——	10.600	8.206	12.000
p	——	<0.05	<0.05	<0.05

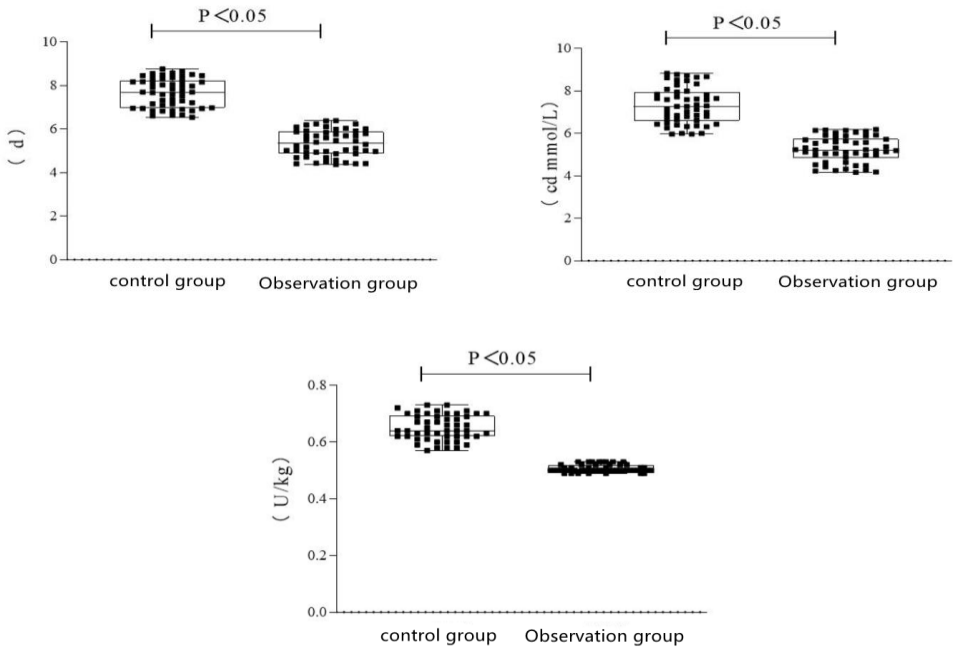

Figure 1. Comparison of blood glucose reaching time, blood glucose drift and insulin dosage between the two groups

2.3 Changes of Blood Glucose Level in the 2 Groups

After treatment, the blood glucose index of the observation group was lower than that of the control group (P<0.05), indicating that CGMS combined with CSII was better than the conventional scheme in controlling blood glucose in the newly diagnosed severe T2DM, as shown in Table 3 and Figure 2.

Table 3. Changes of blood glucose level in 2 groups [(), mmol/L]

group	Number of cases (n)	FPG(mmol/L)		2hPG(mmol/L)		HbAlc(%)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
control group	50	15.67±2.24	8.55±1.03	20.71±5.14	15.68±3.71	11.58±2.27	7.67±0.87
Observation group	50	15.36±3.52	6.22±0.04	21.32±3.47	9.52±1.14	12.32±1.57	6.11±0.65
t	——	0.525	15.980	0.696	11.220	1.896	10.140
p	——	>0.05	<0.05	>0.05	<0.05	>0.05	<0.05

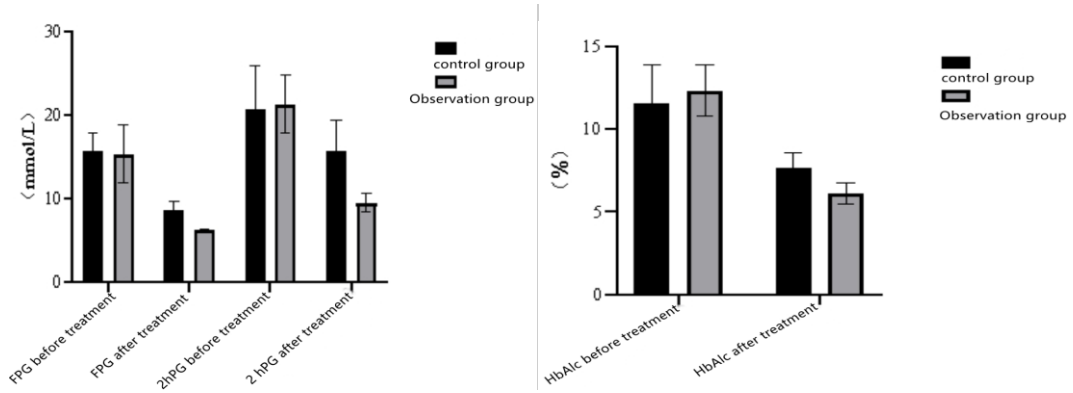

Figure 2. Changes of blood glucose level in 2 groups

2.4 Comparison of Blood Lipid Indexes between the Two Groups

After treatment, the blood lipid indexes in the observation group were better than those in the control group, and the levels of each index were lower than those in the control group (P<0.05), indicating that CGMS combined with CSII was better than the conventional scheme in reducing blood lipid in the newly diagnosed severe T2DM, as shown in Table 4 and Figure 3.

Table 4. Comparison of blood lipid indexes between the two groups [(), mmol/L]

group	Number of cases (n)	TC		TG		LDL-C	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
control group	50	5.45±1.21	4.78±0.34	2.56±0.56	1.95±0.45	4.33±0.78	3.56±0.34
Observation group	50	5.44±1.25	4.01±0.23	2.57±0.55	1.56±0.44	4.36±0.87	3.01±0.23
t	——	0.041	13.260	0.090	4.382	0.182	9.474
p	——	>0.05	<0.05	>0.05	<0.05	>0.05	<0.05

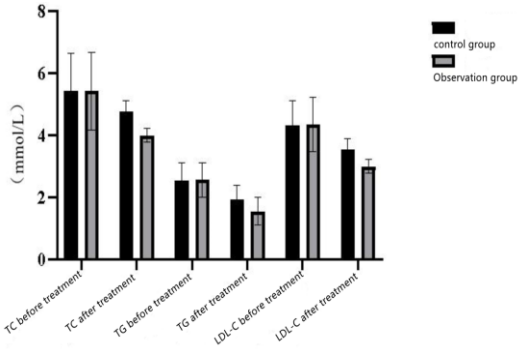

Figure 3. Comparison of blood lipid indicators between the two groups

2.5 Comparison of Safety Indexes between the Two Groups before and After Treatment

Before and after treatment, there was no difference between the two groups in safety assessment related indicators (*P*>0.05), indicating that the safety of the two schemes was equivalent, as shown in Table 5 and Figure 4.

Table 5. Comparison of safety indexes before and after treatment in 2 groups ()

group	Number of cases (n)	ALT(U)		CRE(μmol/L)		BUN(mmol/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
control group	50	25.34±3.45	26.15±3.12	97.65±11.32	96.55±10.34	7.54±1.23	6.92±1.23
Observation group	50	25.45±3.67	26.56±3.45	97.77±11.56	96.89±10.77	7.65±1.34	6.98±1.34
t	——	0.154	0.623	0.052	0.161	0.428	0.233
p	——	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

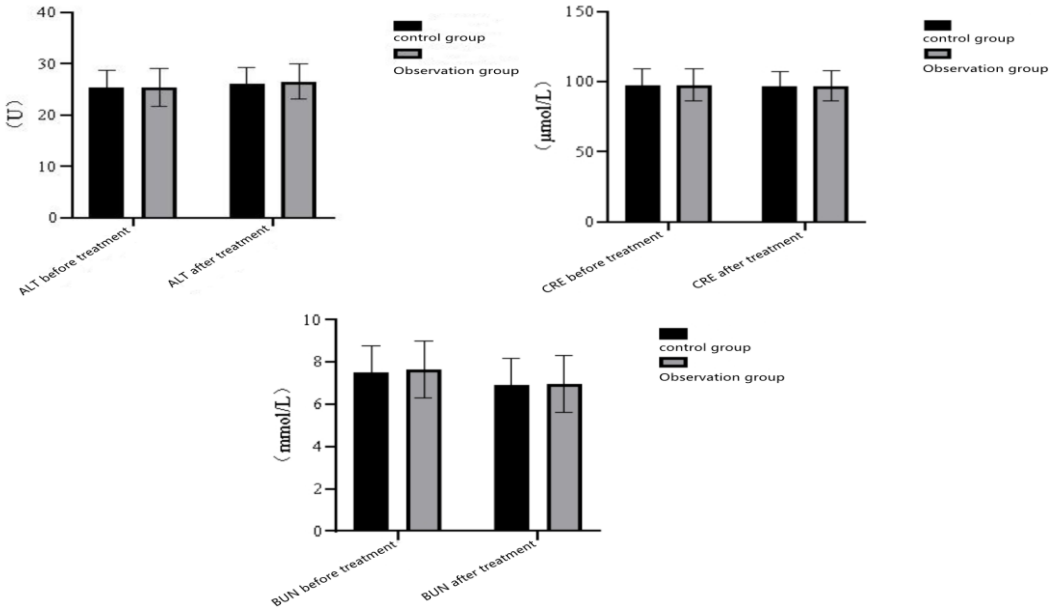

Figure 4. Comparison of safety indexes before and after treatment in two groups

2.6 Comparison of Treatment Effects between the Two Groups

The effective treatment and the incidence of hypoglycemia in the observation group were better than those in the control group ((*P*>0.05), as shown in Table 6.

Table 6. Comparison of therapeutic effects between two groups [n (%)]

group	Number of cases (n)	Effective	Valid	invalid	Effective rate (%)	Incidence of hypoglycemia
control group	50	27	16	7	43(86.00)	9(18.00)
Observation group	50	38	11	1	49(98.00)	1(2.00)
x^2	——	——	——	——	4.891	7.111
P	——	——	——	——	<0.05	<0.05

3. Discussion

Diabetes is a common metabolic disease that seriously endangers human health. Its incidence is related to multiple complex factors such as genetics and environment [11]. The disease is characterized by chronic hyperglycemia [11-13]. According to the data of the International diabetes Alliance on the incidence of diabetes in 2015, the number of adults suffering from diabetes worldwide had reached 382 million by 2013, accounting for 8.3% of the world's population, and continued to grow in all countries. It is estimated that the number of diabetes patients will increase by 55% by 2035, that is, this number may increase to 439 million [14-15]. T2DM patients account for 85%~95%. The main means of clinical prevention and treatment of diabetes and its complications is to control blood sugar. Therefore, how to timely monitor blood sugar changes and control blood sugar levels has become a major and difficult point in clinical research.

In the past, blood glucose monitoring was mainly carried out by finger tip and vein blood sampling. These traditional methods are point monitoring, which can only reflect the current blood glucose value. There is a blind spot for detection and delayed effect for evaluation. It is impossible to understand the continuous blood glucose status and blood glucose dynamic changes of patients through the above monitoring methods, and it is impossible to detect asymptomatic hypoglycemia in time, resulting in missed diagnosis and delayed treatment, and the patient's condition cannot be well understood, It brings a lot of inconvenience to treatment [16-17]. CGMS embeds the glucose sensing chip into the patient's body, which can dynamically collect the patient's blood glucose information and changes in the whole process and all day, thus helping the monitor to timely and accurately understand the blood glucose fluctuation in the patient's body. It can not only guide clinical treatment, timely adjust the insulin dose, but also timely detect the patient's asymptomatic hypoglycemia [18-19]. CSII is currently the main means of intensive treatment for diabetes. This treatment method simulates the normal pancreatic insulin secretion from the perspective of human physiology, and injects micro insulin into the body for a long time all day to improve the islets β Cell function can reduce the output of liver sugar, thus preventing blood glucose fluctuation [20-21]. Research has proved that [22], CSII is easy to operate, can reduce the physical and psychological pain of T2DM patients caused by multiple subcutaneous injections, and improve patients' treatment compliance and self-management. The results of this study showed that the time of blood glucose reaching the standard, blood glucose drift and insulin dosage in the observation group were significantly reduced. This result showed that "double C treatment" could effectively promote the recovery of blood glucose in patients and reduce the dosage of insulin used by patients. It was also

found that the blood glucose level in the observation group decreased significantly after treatment. This suggests that "double C therapy" can effectively promote the blood glucose level of T2DM patients to reach the normal level in a timely manner, and reduce the use of insulin and the occurrence of hypoglycemia. The reason for analysis is that CGMS can collect and store the blood glucose values of patients 24 hours without interruption, and at the same time, it can clarify the impact of exercise, diet and other daily activities on blood glucose, and form blood glucose fluctuation curves in different periods or in the whole period. Doctors can fully and intuitively understand the changes of patients' conditions, and on this basis, formulate the best insulin dosage that is most suitable for patients, and quickly and timely control blood glucose.

Clinical research results show that dynamic blood glucose monitoring can accurately capture the blood glucose fluctuation range that cannot be monitored by conventional fingertip blood glucose monitoring methods, which improves the quality level and work efficiency of blood glucose monitoring to a certain extent, and can more accurately and comprehensively understand the actual blood glucose fluctuation of patients with refractory diabetes [23-24]. In addition, we can also use the blood glucose map of patients monitored by the dynamic blood glucose monitoring system to conduct targeted research and analysis, to clarify the actual impact of patients' eating time and physical exercise behavior on their blood glucose, so as to make up for the shortcomings of conventional blood glucose monitoring methods to some extent [25-26]. The observation in this paper shows that the effective rate of treatment in the observation group is 98%, which is not only better than that in the control group, but also the risk of hypoglycemia is significantly lower than that in the traditional control group. The results suggest that the intervention scheme of "double C treatment" can significantly improve the efficacy of newly diagnosed severe T2DM patients, reduce the incidence of hypoglycemia, and ensure the safety of patients' treatment. The reason may be that the "double C treatment" can clearly analyze the specific causes of patients' hyperglycemia and hypoglycemia as well as the regularity of these hyperglycemia and hypoglycemia, which is helpful for doctors to scientifically formulate personalized control treatment plans, and timely optimize and adjust the patient's medication amount and medication time. Ji Shu et al. [27] also found through research that dynamic blood glucose monitoring combined with continuous subcutaneous insulin infusion can control T2DM blood glucose at an ideal level, reduce the risk of hypoglycemic events, and alleviate the physiological pain caused by repeated measurement of finger tip blood glucose. It is consistent with the results of this study.

To sum up, the combination of CGMS and CSII in T2DM can improve the effect of blood glucose control, reduce the dosage of insulin and the risk of hypoglycemia, and the effect is superior to the traditional scheme.

Funding

If any, should be placed before the references section without numbering.

Data Availability

Data sharing is not applicable to this article as no new data were created or analysed in this study.

Conflict of Interest

The author states that this article has no conflict of interest.

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